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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,306	04/08/2008	Lawrence Solomon	ABT-034	2575

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EXAMINER	
BARHAM, BETHANY P	
ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,306	SOLOMON ET AL.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2010 and 03 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,8-22,24 and 27-43* is/are pending in the application.

4a) Of the above claim(s) *6,11-14,24 and 27-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,8-10,15-22 and 43* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicant's Response and Claim amendments filed on 12/27/10 is also acknowledged. Claims 1-2, 5-6, 8-22, 24, 27-43 are pending and claims 6, 11-14, 24, and 27-42 remain withdrawn. Claims 1, 2, 5, 8-10, 15-22 and 43 are rejected.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/10 has been entered.

It is noted that the species election of 10/31/09 is still maintained and Applicant elected "(a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio)."

NEW OBJECTIONS

Claim 1 is objected to because of the following informalities: "inactive composition" and "inactive segment" which are believed to be referring to the same thing, for clarity and consistency it is suggested that the claim refer to the inactive in the same way (i.e. only "inactive segment"). Appropriate correction is required.

MAINTAINED REJECTIONS

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5, 8-10, 15-22, and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7,329,418. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

NEW:

Claims 1-2, 5, and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6 and 8 of U.S. Patent No. 7,622,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

Response to Arguments

The ODP rejection over US 7,329,418 is maintained as the Terminal disclaimer filed on 05/11/10 was not proper, since the attorney or agent, not of record, was not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c). The person who signed the terminal disclaimer did not have Power of Attorney. The terminal disclaimer for US 7,329,418 must be resubmitted. The terminal disclaimers filed on 11/30/10 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/598267 and 11/569343 have been reviewed and are accepted. The terminal disclaimers have been recorded.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain support for "immediate release inactive composition" or for a tablet of "two layers and three or more segments" as claimed in instant claim 1. While the instant specification does teach an 'inactive segment' [0076, 0080, 0108, 0121, 0125-0126, etc], nowhere is it taught to be 'immediate release inactive composition' or that anything is released (i.e. drug) from the inactive segment since it is inactive. Further the specification teaches tablets of "two substantially identical layers" of immediate release drug at separate ends of a dosage form, separated by an inactive composition [0015, 0020, 0080, etc], it does not teach a tablet of "two layers and three or more segments". Separately tablets of three to five segments are disclosed [0029, 0032, 0068, etc] but nowhere is a tablet of "two layers and three or more segments" disclosed. This is a new matter rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. What is meant by "immediate release inactive composition"? How does it provide a release profile when it does not contain an active? Or rather since it is an inactive composition what is being released? This is confusing and indefinite language.

Claim Rejections - 35 USC § 112

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> A dependent claim is statutorily required to contain a reference to a previous claim in the same application and specify a further limitation of the subject matter claimed.

Claim 2 and dependent claims thereon claims 5, 8-10 and 17) are rejected under 35 U.S.C. 112, fourth paragraph, as being an improper dependent claim. Claim 2 does not further limit the subject matter of claim 1. Claim 1 recites the limitation "three or more segments…and comprises an immediate release inactive composition" (or inactive segment), while claim 2 claims that all 3 segments contain the same drug which is not further limiting.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 5, 8-10, 15-17, 19, 22, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0234608 ('608) in view of US 4,215,104 ('104) and WO 00/18447 ('447).

The instant claims are drawn to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a dose of drug or drugs, in which: said tablet includes two layers and three or more segments or at least three layers forming three or more segments wherein at least one segment is adapted to be broken for dividing the dose prior to administration and comprises an immediate release inactive composition and all segments that contain a pharmacologically effective dose of a drug or drug are immediate release segments that contain the same drug (or combination of drugs at the same ratio), wherein the three-layer tablet has a height greater than its width and the inactive segment has a height greater than the combined height of the active layers.

- '608 teaches a composition/tablet containing multiple layers: an expanding (i.e. inactive) layer and an active ingredient layer (i.e. meeting the limitation of "2 or more segments wherein at least one segment comprises an inactive and all segments that contain a …drug contain the same drug") (abstract, claims 22, 32-

36, 54, 66-67, 72 and 75-76; [0072-0075, 0078, 0082]). According to '608 the compositions are for immediate release ([0029, 0033, 0082], claims 54 and 59). Example 9 teaches an active layer on each side of the expanding layer to form a multilayered composition (i.e. 3 segments) (according to the limitations of claim 1).

- '608 further teaches one or more reservoirs of the same drug, Example 9 teaches a tablet on either side of the expanding layer and an immediate release of methylphenidate is taught and further claims 2 reservoirs tablets of the same active can be compressed with the expanding layer to form the multilayer composition ([0078, 0078, 0185, 0187-0191]; claims 67, 72, 75-77) (according to the limitations of claims 2, 8-9 and 15-17).
- Various drugs are taught for the multilayered tablet of '608 with are known to treat pain, thyroid, etc [0088] (according to the limitations of claim 43).
- '608 does not that the tablet is adapted to be broken for dividing by being scored or marked or that the height of the first layer and third layer is less than the second.
- '104 teaches a multi-fractionable tablet configured in a unitary dosage wile having readily severable sub-dosage units capable of forming bisectional or trisectional fracture and the first and second segments have a mark between them (abstract, Figs.1-15) and the tablets are taller than they are wide (according to the limitations of claims 1 and 10).

- '447 teaches a tablet of one or more drugs for immediate release of at least two drug dosage packages which are placed in an inert coating that is scored, wherein the immediate release (active) compartment is 3/16 diameter round whereas the scored (inactive) compartment is 5/16x3/4 (abstract, pg. 9, Example; Fig. 1), such that the inactive component height of ¾ is greater than the height of both actives (i.e. 6/16) (according to the limitations of claim 5, 19 and 22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '608 with '104 and '447. A skilled artisan desiring to make the known product (ie multilayered tablet) of '608 ready for improvement, with the known technique of formulating a scored product with trisectional segments of '104 which is taller than wide and wherein an intermediate or second segment which is greater in height than the combined active segments and contains a mark/score/indicia of '447 for how to formulate such a segment with predictable results. The combination of a known product '608 ready for improvement with a known technique of scoring and sizing of '104 and '447 is within the purview of the skilled artisan and would yield predictable results.

Claims 1-2, 5, 8-10, 15-22, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0234608 ('608) in view of US 4,215,104 ('104) and WO 00/18447 ('447) and further in view of US 5,118,021 ('021) and US 4,905,589 ('589).

- '608, '104 and '447 are taught above and teach a multilayered scored drug dosage form with an middle expanding pharmaceutical free layer (abstracts,

claims, etc see above) (according to the limitations of instant claim 1-2, 5, 8-10, 15-17, 19, 22, and 43).

- '608, '104 and '447 do not teach that the tablet second segment is of a color which permit identification of said second segment apart from said first or contains printed indicia of instant claims 18 and 20-22.
- '021 discloses that dosage forms, such as tablets, can be marked or scored for splitting and that reasons for reasons for splitting tablets include difficulty of swallowing tablets in whole form and dosage in standard tablet is greater than required (column 1, lines 11-44). '589 discloses that an ink-jet apparatus for marking tablets with appropriate indicia (abstract) (according to the limitations of instant claims 18 and 20-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '608, '104 and '447 with '589 and '021. A skilled artisan desiring to make the known product (ie multilayered tablet) of '608, '104 and '447 ready for improvement, with the known technique of marking a product with a colored indicia of '589 and '021 with predictable results. The combination of a known product '608, '104 and '447 ready for improvement with a known technique '021 and '589 is within the purview of the skilled artisan and would yield predictable results.

Claims 1-2, 5, 8-10, 15-22, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/18447 in view of EP 0348683 and Pharmaceutical Industry Info (2003) and further in view of US 5,118,021 ('021) and US 4,905,589 ('589).

- '447 teaches a multiplex drug delivery system containing two distinct drug dosage packages with equivalent dissolution profiles and/or identical composition for the active provided in an effective amount that is scored and that the drug dosage packages are immediate release form (abstract, pg. 1 lines 8-10; pg. 3, lines 1-5; Fig. 1). According to '447 the same active in the same amount with the same dissolution, that is scored or marked and that the inactive layer is greater in height wherein the immediate release compartment is 3/16 diameter round whereas the scored compartment is 5/16x3/4 (abstract, pg. 1 lines 8-10; pg. 3, lines 1-5; Fig. 1; pg. 9, Example), such that the inactive component height of ¾ is greater than the height of both actives (i.e. 6/16) (meeting the limitations of claim 1-2, 5, 8-10, 17, 19-20 and 22).
- Various drugs are taught for the tablet of '447 with are known to treat arthritis, pain, cardic diseases, etc (pg. 7, lines 5-pg. 8, lines 20) (according to the limitations of claim 43).
- '447 does not teach that the active and inactive components are layered, or an "immediate release" inactive component.
- '683 teaches an immediate release multi-layered tablet wherein the active layers are interspersed with layers containing conventional pharmaceutical excipients such as microcrystalline cellulose (abstract, pg. 4, lines 12-16). Pharmaceutical Industry Info (2003) teaches that the KORSCH TRP 700/900 (tablet press) forms tri-layer and five-layer tablets that have deep filling depths (pg. 2) (see cited as

interest for a visual of the KORSCH TRP 700/900 tablet press) (according to the limitations of claims 1 and 10).

- '447, '683 and Pharmaceutical Industry Info (2002) do not teach colored or printed indicia of instant claims 18 and 20-22.
- '021 discloses that dosage forms, such as tablets, can be marked or scored for splitting and that reasons for reasons for splitting tablets include difficulty of swallowing tablets in whole form and dosage in standard tablet is greater than required (column 1, lines 11-44). '589 discloses that an ink-jet apparatus for marking tablets with appropriate indicia (abstract) (according to the limitations of instant claims 18 and 20-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '447, '683 and Pharmaceutical Industry Info (2002) with '021 or '589. A skilled artisan would know how to substitute the inactive layer of '683 (i.e. microcrystalline cellulose) into the composition of '447 with predictable results. Such a simple substitution of inactive layer for another is within the purview of the skilled artisan and would yield predictable results of an immediate release dosage form. Further a skilled artisan desiring to make the known product (immediate release active components separated by an inactive component) of '447 ready for improvement, with the known technique of formulating multilayered tablet of '683 and Pharmaceutical Industry Info with predictable results. Combination of a known product (substantially identical drug components separated by an inactive component) and a known technique of formulating a multilayered/segmented tablet is within the purview of the skilled artisan

and would yield predictable results. A skilled artisan desiring to make the known product (ie multilayered tablet) of '447, ‘683 and Pharmaceutical Industry Info ready for improvement, with the known technique of formulating a product which contains a mark such as colored/printed indicia of ‘021 and ‘589 with predictable results. The combination of a known scored multilayered product '447, ‘683 and Pharmaceutical Industry Info ready for improvement with a known technique ‘021 and ‘589 is within the purview of the skilled artisan and would yield predictable results.

Cited As Interest

KORSCH TRP 700/900 it is noted that according to the product guide on KORSCH’s website the “KORSCH TRP 700/900” makes multilayered tablets that have a height greater than width and the middle segment can be taller than the other 2 segments and shows each segment a different color with visible marks inbetween segments (see pages 3 and 5).

Response to Arguments

Applicant's arguments with respect to the instant claims have been considered but are moot in view of the new grounds of rejection necessitated by applicants’ amendments.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bethany Barham/
Art Unit 1615